NDA 17-498/S-021

Phannacia & Upjohn
Attention: Mr. Terry L. Reinstein
Regulatory Manager, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

OCT 28 1999

Dear Mr. Reinstein:

Please refer to your supplemental new drug application dated August 26, 1998, received August 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Micronase® (glyburide) Tablets.

We acknowledge receipt of your submission dated September 3, 1999.

This supplemental new drug application provides for the addition of a "Geriatric Use" subsection to the **PRECAUTIONS** section of the package insert per 21 CFR 201.57(f)(10).

The following paragraphs will be added to the end of the **PRECAUTIONS** section, immediately after the "Pediatric Use" paragraph:

> **Geriatric Use:** Elderly patients are particularly susceptible to the hypoglycemic action of glucose lowering drugs. Hypoglycemia may be difficult to recognize in the elderly (see PRECAUTIONS). The initial and maintenance dosing should be conservative to avoid hypoglycemic reactions (see DOSAGE AND ADMINISTRATION).
>
> Elderly patients are prone to develop renal insufficiency, which may put them at risk of hypoglycemia. Dose selection should include assessment of renal function.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted draft labeling dated September 3, 1999. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (dated September 3, 1999).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material.

For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-498/S-021." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we tequest that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. Jena Weber, Regulatory Project Manager, at (301) 827-6422.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research